PROVIDER QUICK POINTS
PROVIDER INFORMATION

BlueCross BlueShield Minnesota

December 13, 2023

Update for New to Market Medical Drugs: Zymfentra

As stewards of healthcare expenditures for our subscribers, we are charged with ensuring our subscribers receive safe, appropriate, and highest quality care while also managing overall costs. As new medical drugs and/or drug indications are approved by the Food and Drug Administration (FDA) for use in the United States, Blue Cross and Blue Shield of Minnesota and Blue Plus (Blue Cross) carefully examines the scientific evidence and outcomes of the drug treatments. Medical drugs are generally administered by infusion or injection by a healthcare professional and process under a subscriber's medical benefit. During the review process, Blue Cross may decide a new to market drug requires further evaluation to determine appropriate coverage or utilization management policies under the medical benefit.

Medical Drug Evaluation Process
As new to market medical drugs are evaluated, Blue Cross's **Medical Drug Evaluation Process** involves clinical review of recent FDA-approved medical drugs or medical drug indications within 6 months of FDA approval. Blue Cross's Medical Policy Pharmacy and Therapeutics Committee carefully examines the scientific evidence and outcomes for each medical drug treatment under consideration. The clinical review includes evaluation of published data and evidence supporting the safety, effectiveness, and the effect of the drug on health outcomes. The Medical Policy Pharmacy and Therapeutics Committee's goal is to find the right balance between making new treatments available and guarding against unsafe or unproven approaches.

While new medical drugs and/or drug indications are under clinical review, the treatment is considered experimental-investigative until the evaluation process has been completed and a determination made if the treatment should be a covered service under the medical benefit. Covered services are determined in accordance with Blue Cross' policies in effect at the time treatment is rendered. Claims submitted while a drug is under review are subject to retrospective review and may be denied.

The drug **Zymfentra (infliximab-dyyb for subcutaneous use)** was approved October 23, 2023, by the FDA for use in the United States and is being added to the **Blue Cross Medical Drug Evaluation Process List for review by our medical policy Pharmacy and Therapeutics Committee.**

While the drug/product is under clinical review, the treatment is considered experimental/investigative until the evaluation process is completed, and a determination made if the treatment should be a covered service under the medical benefit.

Members Impacted
Subscribers with coverage through Commercial health plans (excluding Federal Employee Program (FEP) which has separate requirements).

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Notes

- Providers are encouraged to review the Medical Drug Evaluation Process List periodically for updates.
- Medical drugs do not include drugs that process under the pharmacy benefit, such as self-administered drugs or oral pills which do not need to be given by a health care provider or under their supervision.
- The requirement of Committee Review is a precondition of Blue Cross coverage and applies in addition to all other conditions and terms stated in Blue Cross contracts. For additional information on the Medical Drug Evaluation Process, see **Medical Policy II-174: New FDA-Approved Medical Drugs or Medical Drug Indications**. To access Blue Cross medical policies:
  - Go to providers.bluecrossmn.com
  - Under Medical Management, select “Medical and behavioral health policies”

Questions?

Please contact provider services at **(651) 662-5200** or **1-800-262-0820**.